

IN THE CLAIMS

1. (Cuirrently amended): A modified release dosage form comprising of a high solubility active ingredient wherein the high solubility active ingredient has a solubility where less than 1 part to 30 parts of water is required to dissolve 1 part of active ingredient and said modified release dosage form is prepared by using a dual retard technique to control the release of the high solubility active ingredient, wherein said dual retard technique is a combination of mastrix formulation and reservoir formulation said dosage form comprising a) micro matrix particles containing active ingredient(s) and hydrophobic release controlling agent wherein one or more hydrophobic release controlling agents are selected from the group consisting of ammonio methacrylate copolymers type A and B, methacrylic acid copolymer type A, B and C, poly(methyl methacrylate), poly(ethyl methacrylate), poly(butyl methacrylate), poly(isobutyl methacrylate), poly(hexyl methacrylate), poly(isodecyl methacrylate), poly lauryl methacrylate), poly(phenyl methacrylate), poly(methyl acrylate), poly(isopropyl acrylate), poly(isobutyl actylate), poly(octadecyl acrylate), beeswax, carnauba wax, microcrystalline wax, and ozokerite; fatty alcohols selected from the group consisting of cetostearyl alcohol, stearyl alcohol; cetyl alcohol and myristyl alcohol; and fatty acid esters selected from the group consisting of glyceryl monostearate; glycerol monooleate, acetylated monoglycerides, tristearin, tripalmitin, cetyl esters wax, glyceryl palmitostearate, glyceryl behenate and hydrogenated castor oil and b)a coating of one or more of said hydrophobic release controlling agents on said micro matrix particles whewrein the doisage form reduces the chances of burst effects.

2. (Original): A dosage form as claimed in claim 1, is in the form of tablet.

3. (Canceled)

4. (Previously presented): A dosage form according to claim 1, wherein said hydrophobic release controlling agents are selected from ammonio methacrylate co-polymers.

5. (Previously presented): A dosage form according to claim 4, wherein ammonio methacrylate co-polymers are selected from the group consisting of Ammonio Methacrylate Copolymer type B USP, Ammonio Methacrylate Copolymer type A and Polyacrylate dispersion 30%.

6. (Canceled)

7. (Canceled)

8. (Canceled)

9. (Currently amended): A dosage form according to claim 1, wherein in micro matrix particles, the active ingredient and one or more hydrophobic release controlling agents are present in a ratio of from 100:2.5 to 100: 30.

10. (Previously presented): A dosage form according to one of claims 1-5 wherein in micro matrix particles, the active ingredient can be less than or equal to 1500 mg.

11. (Previously presented): A dosage form according to claim 1,

wherein a coating of one or more hydrophobic release controlling agents on said micro matrix particles are selected from the group comprising of ammonio methacrylate copolymers type A and B, methacrylic acid copolymer type A, B and C, polyacrylate dispersion 30%, polyvinyl acetate dispersion, ethylcellulose, cellulose acetate, cellulose propionate (lower, medium or higher molecular weight), cellulose acetate propionate, cellulose acetate butyrate, cellulose acetate phthalate, cellulose triacetate, poly(methyl methacrylate), poly(ethyl methacrylate), poly(butyl methacrylate), poly(isobutyl methacrylate), poly(hexyl methacrylate), poly(isodecyl methacrylate), poly(lauryl methacrylate), poly(phenyl methacrylate), poly(methyl acrylate), poly(isopropyl acrylate), poly(isobutyl acrylate), poly(octadecyl acrylate), waxes selected from the group consisting of beeswax, carnauba wax, microcrystalline wax, and ozokerite; fatty alcohols -selected from the group consisting of cetostearyl alcohol, stearyl alcohol; cetyl alcohol and myristyl alcohol; and fatty acid esters selected from the group consisting of glyceryl monostearate; glycerol monooleate, acetylated monoglycerides, tristearin, tripalmitin, cetyl esters wax, glyceryl palmitostearate, glyceryl behenate and hydrogenated castor oil.

12. (Previously presented): A dosage form according to claim 11, wherein the hydrophobic release controlling agents are selected from fatty acid esters.

13. (Previously presented): A dosage form according to claim 12, wherein the fatty ester is selected from the group consisting of hydrogenated castor oil and glycerol distearate.

14. (Canceled)

15. (Canceled)

16. (Currently amended): A dosage form according to claim 1, wherein micro matrix particles and coating of one or more hydrophobic release controlling agents are present in a ratio of from 100:2.5 to 100:[[20]] 30.

17. (Previously presented): A dosage form according to claim 1, wherein the high solubility active ingredient is selected from the group consisting of antidiabetic agents, anti-histamines, anti-depressants, anti-viral agents, anesthetics, antacids, anti-arththriics, antibiotics, anti-psychotics, anti-spasmodics, anxiolytic agents, appetite suppressants, cardiovascular agents, cough suppressants, emollients, gastro-intestinal agents, growth regulators, respiratory stimulants, vitamins, angiotensin converting enzyme inhibitors, anti-asthmatics, anti-cholesterolemics, anti-convulsants, anti-depressants, anti-diarrhea preparations, anti-infective, anti-inflammatory agents, anti-nauseants, anti-stroke agents, anti-tumor drugs, anti-tussives, anti-uricemic drugs, amino-acid preparations, antiemetics, antiobesity drugs, antiparasitics, antipyretics, appetite stimulants, cerebral dilators, chelating agents, cholecystokinin antagonists, cognition activators, deodorants, dermatological agents, diuretics, erythropoietic drugs, fertility agents, synthetic hormones, laxatives, mineral supplements, neuroleptics, neuromuscular agents, peripheral vaso-dilators, prostaglandins, vaginal preparations, vaso-constrictors, vertigo agents, biguanides, sulphonylurease, meglitinides, PPAR gama agonist [insulin sensitisers (thiazolidinedione)] and alpha-glucosidase inhibitors.

18. (Original): A dosage form according to claim 1, wherein the high solubility active ingredient is selected from the group comprising of metformin hydrochloride, phenformin, buformin, captopril, ranitidine hydrochloride, potassium chloride, clindamycin, hydroxyurea, erythromycin lactobionate, vancomycin hydrochloride, balsalazide disodium, aminocaproic acid, lisinopril, tramadol, acetaminophen, ciprofloxacin, esters of ampicillin, sodium valproate, niacin, diltiazem, venlafaxine, isosorbide 5-imononitrate, isosorbide dinitrate, pentoxyphylline, propranolol and quetiapine or pharmaceutically acceptable salts thereof.

19-24. (Canceled)

25. (Previously presented): A dosage form according to claim 1, for twice a day administration.

26. (Canceled)

27. (Original): A dosage form according to claim 1, wherein the high solubility active ingredient is niacin.

28. (Previously presented): A modified release dosage form according to claim 27, wherein the composition of the micromatrix particles and coated micromatrix particles is as follows--Micro matrix particles--Niacin 75% w/w to 99% w/w Ammonio Methacrylate Copolymer type B 1% w/w to 25% w/w Coated micro matrix particles Micro matrix particles 70% w/w to 99% w/w Hydrogenated castor oil 1% w/w to 30% w/w Magnesium stearate 0% w/w to 2% w/w.

29. (Original): A dosage form according to claim 1, wherein the high solubility active ingredient is sodium valproate.

30. (Previously presented): A process for the preparation of a modified release dosage form comprising a) preparing a micro matrix particles containing high solubility active ingredient and one or more hydrophobic release controlling agent wherein the ratio of active ingredient(s) and hydrophobic release controlling agent is in the range of 100:2.5 to 100:30 and b) coating the said micromatrix particles containing high solubility active ingredient by one or more hydrophobic release controlling agent, wherein the ratio of micro-matrix particles and hydrophobic release controlling agent is in the range of 100:2.5 to 100:30.

31. (Curently amended): A modified release dosage form comprising of a metformin hydrochloride prepared by using dual retard technique to control the release of metformin, wherein said dual retard technique is a combination of matrix formulation and reservoir formulation said dosage form comprising a) micro matrix particles containing metformin hydrochloride and one or more hydrophobic release controlling agent wherein the ratio of metformin hydrochloride and hydrophobic release controlling agent is in the range of 100:2.5 to 100:30 and b) coating of one or more hydrophobic release controlling agent on micro matrix particles, the ratio of micro-matrix particles and hydrophobic release controlling agent is in the range of 100:2.5 to 100:30 wherein the dosage form reduces the chances of burst effects.

32. (Original): A dosage form as claimed in claim 31, is in the

form of tablet.

33. (Currently amended): A dosage form according to claim 31, wherein the hydrophobic release controlling agents employed for the micro matrix particles are selected from the group consisting of ammonio methacrylate copolymers type A and B USP, methacrylic acid copolymer type A, B and C, polyacrylate dispersion 30%, polyvinyl acetate dispersion, ethylcellulose, cellulose acetate, cellulose propionate (lower, medium or higher molecular weight), cellulose acetate propionate, cellulose acetate butyrate, cellulose acetate phthalate, cellulose triacetate, poly(methyl methacrylate), poly(ethyl methacrylate), poly(butyl methacrylate), poly(isobutyl methacrylate), poly(hexyl methacrylate), poly(isodecyl methacrylate), poly(lauryl methacrylate), poly(phenyl methacrylate), poly(methyl acrylate), poly(isopropyl acrylate), poly(isobutyl acrylate), poly(octadecyl acrylate), waxes selected from the group consisting of beeswax, carnauba wax, microcrystalline wax, and ozokerite; fatty alcohols selected from the group consisting of cetostearyl alcohol, stearyl alcohol; cetyl alcohol and myristyl alcohol; and fatty acid esters selected from the group consisting of glyceryl monostearate; glycerol monooleate, acetylated monoglycerides, tristearin, tripalmitin, cetyl esters wax, glyceryl palmitostearate, glyceryl behenate and hydrogenated castor oil.

34. (Previously presented): A dosage form according to claim 33, wherein the hydrophobic release controlling agents are selected from ammonio methacrylate co-polymers.

35. (Previously presented): A dosage form according to claim 34, wherein the ammonio methacrylate co-polymers are selected

from the groups consisting of Ammonio Methacrylate Copolymer type B, Ammonio Methacrylate Copolymer type A and Polyacrylate dispersion 30%.

36-39. (Canceled)

40. (Previously presented): A dosage form according to one of claims 31-34, wherein in micro matrix particles, metformin hydrochloride can be less than or equal to 1500 mg.

41. (Previously presented): A dosage form according to claim 31, wherein the coating of one or more hydrophobic release controlling agents on said micro matrix particles are selected from the group consisting ammonio methacrylate copolymers type A and B, methacrylic acid copolymer type A, B and C, polyacrylate dispersion 30%, polyvinyl acetate dispersion, ethylcellulose, cellulose acetate, cellulose propionate (lower, medium or higher molecular weight), cellulose acetate propionate, cellulose acetate butyrate, cellulose acetate phthalate, cellulose triacetate, poly(methyl methacrylate), poly(ethyl methacrylate), poly(butyl methacrylate), poly(isobutyl methacrylate), poly (hexyl methacrylate), poly(isodecyl methacrylate), poly (lauryl methacrylate), poly(phenyl methacrylate), poly (methyl acrylate), poly (isopropyl acrylate), poly (isobutyl acrylate), poly (octadecyl acrylate), waxes selected from the group consisting of beeswax, carnauba wax, microcrystalline wax, and ozokerite; fatty alcohols selected from the group consisting of cetostearyl alcohol, stearyl alcohol; cetyl alcohol and myristyl alcohol; and fatty acid esters selected from the group consisting of glyceryl monostearate; glycerol monooleate, acetylated monoglycerides, tristearin, tripalmitin, cetyl esters wax,

glyceryl palmitostearate, glyceryl behenate and hydrogenated castor oil.

42. (Previously presented): A dosage form according to claim 41, wherein the hydrophobic release controlling agents are selected from fatty acid esters.

43. (Previously presented): A dosage form according to claim 42, wherein fatty acid ester is selected from the group consisting of hydrogenated castor oil and glycerol distearate.

44-46. (Canceled)

47. (Previously presented): A modified release dosage form according to claim 31, wherein the composition of the micromatrix particles and coated micromatrix particles is as follows--Micro matrix particles--Metformin hydrochloride 75% w/w to 99% w/w Ammonio Methacrylate Co-polymer type B USP 1% w/w to 25% w/w Coated micro matrix particles Micro matrix particles 70% w/w to 99% w/w Hydrogenated castor oil 1% w/w to 30% w/w Magnesium stearate 0% w/w to 2% w/w.

48. Canceled)

49. (Original): A dosage form according to claim 31, is once a day oral formulation.

50-57. (Canceled)

58. (Original): A dosage form as claimed in claim 1, wherein the

said dosage form may optionally contain more than one high solubility active ingredient.

59. (Original): A dosage form as claimed in claim 31, wherein the said dosage form may optionally contain more than one antidiabetic active ingredient.

60. (Previously presented): A process for the preparation of a modified release dosage form comprising a) preparing a micro matrix particles containing metformin hydrochloride and one or more hydrophobic release controlling agent(s) wherein the ratio of metformin hydrochloride and hydrophobic release controlling agent is in the range of 100:2.5 to 100:30 and b) hydrochloride by one or more hydrophobic release controlling agent, wherein the ratio of micro-matrix particles and hydrophobic release controlling agent is in the range of 100:2.5 to 100:30.

61. (Previously presented): A dosage form according to claim 1, for once a day administration.